Remarks

A. Summary of Amendment to the Claims

By the present Amendment, no claims have been amended. Thus, upon entry of the present Response, claims 1, 3, 4, and 6-10 remain pending and under examination.

B. Rejection Under 35 U.S.C. §112, first paragraph - Enablement

In the Final Office Action mailed July 30, 2009 the examiner rejected claims 1, 3, 4, and 6-10 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Applicants respectfully traverse the rejection.

Specifically, the examiner alleged that:

> "…the specification fails to demonstrate that the claimed transgenic rats develop active HIV infection, express antibodies, and viral antigen in sera as claimed. There is no guidance or evidence of record that shows that the transgenic rats of the instant invention develop active HIV infection after exposure to HIV, with expression of antibodies of viral antigen in sera thereof." (Final Office Action mailed July 30, 2009, p. 4.)

Applicants respectfully disagree with these conclusions.

A determination of enablement under 35 U.S.C. §112, first paragraph is based on an evaluation of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the relevant art to make and use the claimed invention without "undue experimentation." The disclosure of the present application is fully enabling, as meeting such requirement.

The examiner's attention is respectfully drawn to the Declaration of Inventor Joseph Bryant filed on November 20, 2008, which is required to be considered on the enablement issue, consistent with the directions in MPEP §2164.05 that:

> "The examiner must then weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection and decide whether the claimed invention is enabled…The determination should always be based on the weight of all the evidence." (Emphasis added.)

In view of all of the disclosure in the specification of the present application and the further evidence of enablement provided in Dr. Bryant's Declaration, the claimed invention is fully compliant with the statutory requirements of 35 U.S.C. §112, first paragraph.

Example 11, for example, demonstrates the steps for making a rat transgenic for human CD4, as has been noted by the examiner. Further to Example 11, Dr. Bryant's Declaration affirmatively states that:

> "5. Human CD4 transgenic rats have been produced by our lab according to the methods set forth in the application as discussed below and confirmed by experimental data…" (Emphasis added.)

The Bryant Declaration and therefore clearly evidences that the disclosure in the application enables a CD4 transgenic rat to be produced and used, according to the methodology set forth in the application.

Dr. Bryant's Declaration also states that:

> "8. The hCD4 transgenic rat was infected with HIV-1 according to the specific disclosure of Example 11 of the application…"(Emphasis added.)

Example 11 of the application describes HIV infection of the CD4 transgenic rat:

> "Infection of hCD4 transgenic rats with HIV can be performed as follows. Mature (6 to 8 weeks old transgenic rats can be inoculated either intravenously (IV) or intraperitoneally (IP) with various concentrations of HIV (IIIB) (0.1-20 $TCID_{50}$) or with 10^5 HIV-1 (IIIB)-infected CEM cells. Alternatively, the rats can be infected with a T cell tropic HIV isolate…"

and Example 11 of the application further describes assay of sera of the CD4 transgenic rat for HIV-1 antibodies and viral antigen:

> "The presence of HIV-1 antibodies and viral antigen (p24) in the sera can then be analyzed every 2 weeks for the first two months and at 4 months post inoculation using a commercially available ELISA test."

Accordingly, such specification disclosure and Declaration evidence provided by the inventor requires the conclusion that one of skill in the art, on the basis of the disclosure of the invention in the present application, ca, without undue experimentation, generate a transgenic CD4 rat, infect such rat with HIV and evaluate the sera of the infected rat for the presence of HIV-1 antibodies and viral antigen. Claims 1, 3, 4, and 6-10 therefore satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is correspondingly requested.

C. Rejection Under 35 U.S.C. §112, second paragraph - Indefiniteness

In the Final Office Action mailed July 30, 2009 the examiner rejected claim 1, and claims 3, 4, and 6-10 dependent therefrom, for containing the language "…active HIV infection after exposure to HIV…" alleging that such recitation was indefinite, based on the assertion that "the properties encompassed by 'active HIV infection' are not apparent." (Final Office Action mailed July 30, 2009, p. 7.) Applicants respectfully traverse this rejection.

The definiteness requirement of 35 U.S.C. §112, second paragraph requires that a claim particularly point out and distinctly claim the subject matter of the invention, such that ""the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent." (MPEP §2173). Claim 1 satisfies such requirement in its recital of "…active HIV infection after exposure to HIV…"

It is well known that an infection is a condition resulting from invasion of a host by an infectious organism. In the case of HIV infection, the HIV can exist in the host in either an active state or a latent state. This is also well known. The active state is characterized by the exhibition of disease symptoms, while a latent infection involves dormancy of the infectious organism within the host.

The specification repeatedly describes the generation of a transgenic rat useful as disease model, where the transgenic rat exhibits symptoms of HIV infection, *e.g.,* in the specification at page 6, lines 17-21; page 10, lines 25-27; page 26, line 25 to page 27, line 2; and in original claim 18, with active HIV infection being evidenced, as recited in claim 1, by "expression of antibodies or viral antigen in sera" of the rat.

Accordingly, "…active HIV infection after exposure to HIV…" is clear and definite, as evidenced by "expression of antibodies or viral antigen in sera" expressly recited in claim 1. Claim 1 and claims 3, 4, and 6-10 dependent thereunder, fully comply with the requirements of 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection is correspondingly requested.

CONCLUSION

Based on the foregoing, all of Applicants' pending claims 1, 3, 4, and 6-10 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance.

The time for responding to the July 30, 2009 Office Action without extension was set at three months, or October 30, 2009. This Response is therefore timely and no fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

/steven j. hultquist/
Steven J. Hultquist
Reg. No. 28,021
Attorney for Applicant(s)

/kelly k. reynolds/
Kelly K. Reynolds
Reg. No. 51,154
Attorney for Applicant(s)

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 4115-150-CIP-DIV

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